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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,464	NYLESE, TARA	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *2-9 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 10-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Applicant's filing of the Appeal Brief on May 1, 2007 is acknowledged. After review of the Brief, the finality of the previous office action is withdrawn.

Currently, claims 1 and 10 – 21 are pending and under examination.

Withdrawn Objections and Rejections

The previous objections to the claims are withdrawn in view of Applicant's amendments filed December 6, 2006.

The previous rejection of claim 1 under 35 U.S.C. 103(a) is withdrawn in view of Applicant's arguments filed May 1, 2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Becket (US 5,710,372).

Becket teaches a method of monitoring temporal changes of analyte levels in a source, preferably an aqueous fluid composition, said method comprising:

providing multiple unitary test devices, each unitary test device including a plurality of test regions, each test region responsive at a different sensitivity level to indicate the presence of the analyte in the source;

bringing a sample from the source into contact with a first of the unitary test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more regions of the first test device;

subsequently bringing a different sample from the same source into contact with a second of the unitary test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more regions of the second unitary test device, said responses providing information about temporal changes in analyte concentration (see Figures 1-4a; column 1, lines 14-36 and lines 66-67; column 2, lines 1-41; column 3, lines 59-67; column 4, lines 1-44; column 5, lines 19-32 and lines 60-67; column 6, lines 1-60; column 7, lines 1-54; column 10, lines 43-51; column 11, lines 39-63; and column 14, lines 26-30).

Claims 10 – 16 and 19 – 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer et al. (WO 98/39657).

Boehringer et al. teach a lateral flow assay method for monitoring changes in analyte concentration (level) in a sample (source), the method comprising: defining

multiple measurable distinguishable sensitivity level each indicative of a different amount, i.e. concentration, of analyte in the source;

providing a first test matrix (unit) including a first capture line (region) thereon responsive to the presence of analyte in the sample at a first of the sensitivity levels;

providing a second test matrix (unit) including a first capture line (region) thereon responsive to the presence of analyte in the sample at a second of the sensitivity levels;

providing a first sample from one source;

bringing the first sample into contact with the first test matrix to provide the first capture line thereon an opportunity to indicate the presence of analyte in the sample at at least the first level;

providing a second sample from the same source on an occasion subsequent to providing the first sample; and

bringing the second sample into contact with the second test matrix to provide the first capture line thereon an opportunity to indicate presence of analyte in the sample at at least the second level (see Figure 3; and p4, lines 22-38; p5, lines 1-2; p6, lines 26-34; p13, lines 27-37; p14, lines 6-27; p15, lines 29-32; p23, lines 7-25; p29, lines 35-38; p30, lines 1-21; Example 6 on p48; and "Multiple lane lateral flow test devices" on p52-54).

With respect to Applicant's claims 11 – 13, the first test matrix can include a second capture line responsive to presence of the second level of analyte and the step of bringing the first sample into contact with the first test matrix includes providing said second capture region an opportunity to indicate the presence of analyte in the sample

at at least the second level, wherein the second capture line is a measurably distinguishable sensitivity level different than the first of the sensitivity levels, or wherein the first and second sensitivity levels are the same (see Figure 3; and p6, lines 1-7; p13, lines 27-30; p14, lines 6-27; p15, lines 29-32; Example 1 on p39; and Example 6 on p48).

With respect to Applicant's claim 14, the second test matrix includes a second capture line thereon responsive to the presence of the analyte in the source at the first of the sensitivity levels (see Figure 3; and p6, lines 1-7; p13, lines 27-30; p14, lines 6-27; p15, lines 29-32; Example 1 on p39; and Example 6 on p48).

With respect to Applicant's claims 15 and 16, the first and second test matrices can include forming thereon at least three capture lines each responsive to the presence of the analyte in the source at a different of the multiple distinguishable sensitivity levels (see Figure 3; and p6, lines 1-7; p13, lines 27-30; p14, lines 6-27; and p15, lines 29-32).

With respect to Applicant's claim 19, the step of defining the multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the sample is accomplished by forming at least the first capture lines (see Figure 3; and p4, lines 22-38; p5, lines 1-2; and p6, lines 26-30).

With respect to Applicant's claim 20, the method is already discussed above for claim 10, additionally as seen in Figure 3, up to three test units are presented.

With respect to Applicant's claim 21, a substrate 20 is provided to adhere the test units to (see Figure 3).

Claims 10, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Kenjyou et al. (US 2004/0096985).

Kenjyou et al. teach a method for monitoring changes in analyte level of a sample source, wherein the method comprises: defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the sample source;

providing a first test unit including a first region thereon responsive to the presence of analyte in the source at a first of the sensitivity levels;

providing a second test unit including a first region thereon responsive to the presence of analyte in the source at a second of the sensitivity levels;

providing a first sample from the sample source;

bringing the first sample into contact with the first unit to provide the first region thereon an opportunity to indicate presence of analyte in the sample at at least the first level;

providing a second sample from the source on an occasion subsequent to providing the first sample; and

bringing the second sample into contact with the second unit to provide the first region thereon an opportunity to indicate presence of analyte in the sample at at least the second level (see Figure 2; and paragraphs [0015], [0019], [0021], [0027], [0059], [0061], [0070], [0076], [0080], [0123], [0131], [0143]-[0145], [0161], [0165], [0189] and [0193]).

With respect to Applicant's claim 19, the step of defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source is accomplished by forming at least the first regions (see Figure 2; and paragraphs [0143]-[0145], [0189] and [0193]).

With respect to Applicant's claim 20, the method is already discussed above for claim 10, additionally as seen in Figure 2, up to five test units are presented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al. (WO 98/39657) in view of Cole (US 6,656,745).

The Boehringer et al. reference, which was discussed in the 102(b) rejection above, fails to teach that at least one of the three regions of the first matrix (unit) is responsive to substantially the same level of analyte as one of the three regions in the second matrix (unit), or that each of the regions of the first matrix is responsive to substantially the same level of analyte as one of the regions of the second.

Cole teaches a device and method for multi-level, semi-quantitative immunodiffusion assay. The device utilizes a plurality of binding zones wherein the concentration of binding agent immobilized determines a sensitivity of a given binding zone. Individual binding zones can be reactive for pre-determined levels of analyte in a sample, i.e. each binding zone has a specified concentration of binding reagent. Therefore, the binding zones allow for testing of an analyte over a broad range of concentration. The device normally involves a three-binding zone device or "tri-level test." The number of levels can be tailored in combination with the concentration of binding reagents to alter the sensitivity of the semiquantitative analysis depending on the particular application or desired precision. The device can detect for the presence or absence of the analyte, i.e. by determining trace levels of the analyte, as well as the semiquantitative amount of analyte present. Thus, the device is beneficial to screen for detection and progress of a particular medical condition, e.g. one threshold level can indicate that the condition is at a preliminary stage, whereas another threshold amount can indicate that the condition is in an advanced state. Such devices are beneficial for testing of analytes that occur in a range, such as prostate specific antigen (PSA) or pregnancy hormone (HCG), whose concentration range determines what, if any medical

action is necessary (see column 5, lines 16-67; column 6, lines 7-48; and column 7, lines 16-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include substantially the same sensitivity level in one of the three regions found in both the first and second matrices of Boehringer et al. because Cole teaches the benefit of using a "tri-level test" wherein one of the three regions tests for trace levels of the analyte in order to determine if the analyte is in fact present or absent within the sample. It also would have been obvious to create the regions of the first unit to be responsive to substantially the same level of analyte as only one of the regions of the second in order to allow for testing of an analyte over a broad range of concentration as taught by Cole because Cole teaches the benefit of semiquantitative testing of analytes that occur in a range, such as prostate specific antigen (PSA) or pregnancy hormone (HCG), whose concentration range determines what, if any medical action is necessary.

Response to Arguments

Applicant's arguments filed May 1, 2007 have been fully considered but they are not persuasive with respect to the 35 U.S.C. 102 rejections over the Boehringer et al. and the Kenjyou et al. references. The main arguments presented by Applicant include:

1) Neither the Boehringer et al. or Kenjyou et al. references teach a method of monitoring **changes** in analyte levels;

2) Neither the Boehringer et al. or Kenjyou et al. references teach multiple "test units;" and

3) Neither the Boehringer et al. or Kenjyou et al. references teach providing a second sample from the source on an occasion subsequent to providing the first sample.

With regard to Applicant's first argument, both Boehringer et al. and Kenjyou et al. teach a method of monitoring "changes" in analyte levels, wherein each of the multiple "test units" provided by Boehringer et al. and Kenjyou et al. include a measurably distinguishable sensitivity level that is different from the previous "test unit." In particular, Boehringer et al. teach a device including at least 3 "test units," wherein each unit includes a sample receiving pad 12 and a capture zone 16, and each capture zone has a different sensitivity or affinity for the analyte of interest. The separate sample receiving pads require the user to apply a sample to each of the test units individually, and therefore a first sample is applied to the first sample receiving pad of the first test unit, and subsequently a second sample is applied to the second sample receiving pad of the second test unit. After application of the sample to each of the test units, the "change" in analyte level can be monitored by visually identifying the signals created in each of the capture zones of the multiple test units, wherein a signal in the first capture zone of the first test unit would indicate a level of analyte in the test sample as being at one concentration, a signal in the second capture zone of the second test unit would indicate a different level of analyte in the test sample as being at a second concentration, and so on. Therefore, Boehringer et al. does in fact teach the monitoring

of "changes" in analyte levels (see Figure 3; and p4, lines 22-38; p5, lines 1-2; p6, lines 26-34; p13, lines 27-37; p14, lines 6-27; p15, lines 29-32; p23, lines 7-25; p29, lines 35-38; p30, lines 1-21; Example 6 on p48; and "Multiple lane lateral flow test devices" on p52-54). The method and device of the Kenjyou et al. reference, which was discussed in the 102(e) rejection above, operates in a similar manner as the Boehringer et al. reference, and therefore also teaches the monitoring of "changes" in analyte levels (see Figure 2; and paragraphs [0015], [0019], [0021], [0027], [0059], [0061], [0070], [0076], [0080], [0123], [0131], [0143]-[0145], [0161], [0165], [0189] and [0193]). Additionally, the methods recited in Applicant's claims 10 and 20 do not require the monitoring of "temporal changes" in analyte levels, but merely the monitoring of "changes" in analyte levels.

With regard to Applicant's second argument, both Boehringer et al. and Kenjyou et al. teach providing first and second test units, wherein each unit contains at least one capture or detection zone that indicates the presence of the analyte in a sample at a certain level. The "units" of Boehringer et al. are presented most accurately in Figure 3 of the reference, wherein each "unit" comprises a test strip containing at least one capture zone, wherein the strips are connected to a main backing. Similarly, Kenjyou et al. teach a plurality of test "units" that are each connected together (see Figures 2 and 7). However, Applicant's recitation for the first and second "test units" in claims 10 and 20 do not teach away from these embodiments for the test units taught by Boehringer et al. and Kenjyou et al. Therefore, both Boehringer et al. and Kenjyou et al. anticipate the first and second test units of Applicant's claims 10 and 20.

With regard to Applicant's third argument, both Boehringer et al. and Kenjyou et al. teach providing first and second samples to the plurality of test units, wherein the samples can be provided from the same source at subsequent occasions. Applicant does not specify what exactly is meant by " an occasion subsequent," and therefore, as long as both references teach applying the sample to the units one at a time, this anticipates a "subsequent occasion." With respect to the Boehringer et al. reference, the embodiment presented in Figure 3 allows for a sample to be applied onto each sample receiving pad at a subsequent time in order for the concentration of an analyte in a sample to be determined (see Figure 3; and p29, lines 34-38; p30, lines 1-38; and p31, lines 1-7). With respect to the Kenjyou et al. reference, the embodiment of Figure 2 allows for a sample to be applied into the inlet of each unit separately, i.e. on subsequent occasions, in order for the concentration of the analyte in the sample to be determined (see Figure 2; and paragraphs [0123] and [0143]-[0145]).

Therefore, the references of Boehinger et al. and Kenjyou et al. anticipate Applicant's claims 10 and 20.

Conclusion

No claims are allowed.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Jordan (US 3,006,735); and

Hochstrasser (US 4,042,329).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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